

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE # 6

Applicant(s) : WILBER, et al.

11-13-00
Dm

U.S. Serial No.: 09/519,998

Examiner: Unassigned

Filed: March 6, 2000

Group Art Unit: 1616

For: TRIFUNCTIONAL REAGENT FOR CONJUGATION TO A BIOMOLECULE

INFORMATION DISCLOSURE STATEMENTAssistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. § 1.56, Applicants bring the following documents to the attention of the Examiner in the above-captioned patent application:

- 1) U.S. Patent Application No. 5,474,772 to Maddock, dated December 12, 1995;
- 2) European Patent Application No. EP 0 567 514 B1 to Nilsson, et al., dated November 11, 1993;
- 3) PCT Patent Application No. WO91/01749 to Maddock, dated February 21, 1991;
- 4) Australian Patent No. AU-B-64268/90 to Maddock, dated March 11, 1991;
- 5) "Radioimmunosintigraphy with technetium-99m-labelled monoclonal antibody, SM3, in gynaecological cancer," authored by M. Granowska, et al., featured in *European Journal of Nuclear Medicine*, Vol. 20, No. 6, June 1993, pp. 483-489;
- 6) "Radioimaging of Melanoma Using ^{99m}Tc-labeled Fab Fragment Reactive with a High Molecular Weight Melanoma Antigen," authored by Lamk M. Lamki, et al., featured in *Cancer Research (Suppl.)*, 50, February 1, 1990, pp. 904s-908s;
- 7) "Clinical Studies of Cancer Radioimmunodetection with Carcinoembryonic Antigen Monoclonal Antibody Fragments Labeled with ¹²³I or ^{99m}TC," authored by David M.



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Goldenberg, et al., featured in *Cancer Research (Suppl.)*, 50, February 1, 1990, pp. 909s-921s;

- 8) "Clinical Experience with Iodine-123-Iodophenylpentadecanoic Acid," authored by James Corbett, featured in *The Journal of Nuclear Medicine*, Vol. 35, No. 4 (Suppl), April, 1994, pp. 32S-37S;
- 9) "Preliminary Report of an Ongoing Phase I/II Dose Range, Safety and Efficacy Study of Iodine-123-Phenylpentadecanoic Acid for the Identification of Viable Myocardium," authored by C. Hansen, featured in *The Journal of Nuclear Medicine*, Vol. 35, No. 4 (Suppl), April, 1994, pp. 38S-42S;
- 10) "Localization of Cognitive Operations in the Human Brain," authored by Michael I. Posner, et al., featured in *Science*, Vol. 240, June 17, 1988, pp.1627-1631;
- 11) "Cardiac SPECT with Iodine-123-Labeled Fatty Acids: Evaluation of Myocardial Viability with BMIPP," authored by F.F. (Russ) Knapp, et al., featured in *The Journal of Nuclear Medicine*, Vol. 36, No. 6, June, 1995, pp. 1022-1030;
- 12) "Phase I/II Clinical Radioimmunotherapy with an Iodine-131-Labeled Anti-Carcinoembryonic Antigen Murine Monoclonal Antibody IgG," authored by Thomas M. Behr, et al., featured in *The Journal of Nuclear Medicine*, Vol. 38, No. 6 June, 1997, pp. 858-870;
- 13) "Phase I Radioimmunotherapy Trial with Iodine-131-CC49 in Metastatic Colon Carcinoma," authored by C.R. Divgi, et al., featured in *The Journal of Nuclear Medicine*, Vol. 36, No. 4 April, 1995, pp. 586-592;
- 14) "Yttrium-90/Indium-111-DOTA-Peptide-Chimeric L6: Pharmacokinetics, Dosimetry and Initial Results in Patients with Incurable Breast Cancer," authored by Sally J. Denardo, et al., featured in *Anticancer Research*, Vol. 17, 1997, pp. 1735-1744;

- 15) "Experimental Radiotherapy of Receptor-Positive Human Prostate Adenocarcinoma With ^{188}Re -RC-160, A Directly-Radiolabeled Somatostatin Analogue," authored by Paul O. Zamora, et al., featured in *Int. J. Cancer*, Vol. 65, 1996, pp. 214-220;
- 16) "Regulation of Tumor Cell Growth: Experimental Approaches and Clinical Oncology -- Somatostatin Analogues for Somatostatin-Receptor-Mediated Radiotherapy of Cancer," authored by B. Stolz, et al., featured in *Digestion*, Vol. 57 (suppl 1), 1996, pp. 17-21;
- 17) "ZD2767, an Improved System for Antibody-directed Enzyme Prodrug Therapy That Results in Tumor Regressions in Colorectal Tumor Xenografts," authored by David C. Blakey, et al., featured in *Cancer Research*, Vol. 56, July 15, 1996, pp. 3287-3292;
- 18) "Clearance of circulating radio-antibodies using streptavidin or second antibodies in a xenograft model," authored D. Marshall, et al., featured in *Br. J. Cancer*, Vol. 69, 1994, pp. 502-507;
- 19) "Clinical Aspects of Local and Regional Tumor Therapy with ^{188}Re -RC-160," authored by H. Bender, et al., featured in *Anticancer Research*, Vol. 17, 1997, pp. 1705-1712;
- 20) "Blood Clearance of Radiolabeled Antibody: Enhancement by Lactosamination and Treatment with Biotin-Avidin or Anti-Mouse IgG Antibodies," authored by Alexander L. Klibanov, et al., featured in *The Journal of Nuclear Medicine*, Vol. 29, No. 12, December, 1988, pp. 1951-1956;
- 21) "Improved Characteristics of a Human β -Glucuronidase-Antibody Conjugate after Deglycosylation for Use in Antibody-Directed Enzyme Prodrug Therapy," authored by Pieter H. J. Houba, et al., featured in *Bioconjugate Chem.*, Vol. 7, No. 5, 1996, pp. 606-611;
- 22) "Site-Specific Prodrug Activation by Antibody- β -Lactamase Conjugates: Preclinical Investigation of the Efficacy and Toxicity of Doxorubicin Delivered by Antibody

Directed Catalysis," authored by Damon L. Meyer, et al., featured in *Bioconjugate Chem.*, Vol. 6, No. 4, 1995, pp. 440-446;

23) "Avidin and Streptavidin," authored by N. Michael Green, featured in *Methods in Enzymology*, Vol. 184, 1990, pp. 51-67; and

24) "Avidin," authored by N. Michael Green, featured in *Adv. Prot. Chem.*, Vol. 29, 1975, pp. 85-132.

A PTO-1449 form listing these documents is enclosed.

This Information Disclosure Statement is intended to be in full compliance with the rules, but should the Examiner find any part of its required content to have been omitted, prompt notice to that effect is earnestly solicited, along with additional time under Rule 97(f), to enable Applicants to comply fully.

Consideration of the foregoing and enclosures plus the return of a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column per MPEP 609 are earnestly solicited along with an early action on the merits.

If any fees are required to facilitate consideration of this Information Disclosure Statement, the fees can be charged to Deposit Account No. 02-4300.

Respectfully submitted,

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